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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARY BOWEN **2819 State Highway 10, P. O. Box 15** **Summit, New York 12175** **AND** **IVA LANG AND RONALD J. LANG, H/W** **7950 Grafton Avenue South** **Cottage Grove, MN 55016** *Plaintiffs,* v. **MERCK & CO.** **770 Sumneytown Pike** **West Point, PA 19486** **PETER S. KIM, Ph.D.** **119 Henning Drive, North Wales, Montgomery County, PA 19446.** **LOUIS M. SHERWOOD, Ph.D.** **1241 Forest Hill Drive, Lower Gwynedd, PA** **DAVID W. ANSTICE,** **5280 Militia Hill Road,** **Plymouth Meeting, PA** **and** **EDWARD M. SCOLNICK, M.D.,** **1201 Magnolia Drive, Wayland,** **Middlesex County, MA 01778.** *Defendant(s)*	**CIVIL ACTION NO. _____** **COMPLAINT** **JURY TRIAL DEMANDED**

PLAINTIFFS' COMPLAINT

Plaintiffs, Mary Bowen and Iva and Ronald J. Lang, by and through their undersigned counsel, do hereby aver as follows:

PARTIES

1. Plaintiff, Mary Bowen, (hereinafter "Plaintiff") is an individual and citizen and resident of the State of New York, residing at the address listed in the caption above.

2. Plaintiff, Iva Lang, (hereinafter "Plaintiff") is an individual and citizen and resident of the State of Minnesota, residing at the address listed in the caption above.

3. At all times relevant herein, defendant, Merck & Company, Inc. (hereinafter "Merck" or "defendants") is a business entity as listed in the caption and is a citizen of the United States, is a citizen of a state other than New York and Minnesota and maintains a principal places of business in a state other than New York and Minnesota as listed in the caption.

4. At all material times herein, defendants were, and are, in the business of profiting from the design, manufacture, marketing, distribution and/or sales of the brand-name prescription drug Vioxx (Rofecoxib).

5. At times relevant and material hereto, Defendants have sold, distributed and marketed either directly or indirectly through third-parties or related entities, the pharmaceutical drug Vioxx in the Commonwealth of Pennsylvania.

6. Defendant Peter S. Kim, Ph.D. (hereinafter "Dr. Kim") is a citizen of Pennsylvania, residing therein at 119 Henning Drive, North Wales, Montgomery County, Pennsylvania 19446. Dr. Kim was Executive Vice President of Research and Development of Merck Research Laboratories from 2001 to 2002 and is currently President of Merck Research Laboratories and a member of

Defendant Merck's Management Committee.

7. At all times relevant hereto, Dr. Kim was in charge of the scientific development, testing, and the development and promulgation of product safety warnings for Vioxx. At all times pertinent hereto, Dr. Kim was a primary decision maker in regard to Vioxx. In his positions as Executive Vice President of Research and Development and then as President of Merck Research Laboratories, Dr. Kim was responsible to protect the safety of consumers, including the Plaintiffs, by providing adequate warnings of the risks of Vioxx, including myocardial infarction and stroke.

8. Dr. Kim knew, or in the reasonable exercise of care, should have known, that Vioxx was unsafe and subjected consumers, including Plaintiffs herein, to the risk of injuries including myocardial infarction and stroke, yet Dr. Kim failed to provide adequate warnings regarding such risks.

9. Dr. Kim knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe, yet he withheld that information from consumers, including Plaintiffs, while providing false assurances of safety, which were provided not only to physicians, but directly to consumers.

10. Dr. Kim failed to exercise reasonable care as set forth above and thus, consumers, including Plaintiffs, were subject to an increased risk of harm of myocardial infarction and stroke. Dr. Kim had undertaken the responsibility of ensuring and promoting drug safety for consumers of Vioxx, including Plaintiffs herein. Plaintiffs have been injured as a proximate cause of Dr. Kim's failure to exercise reasonable care in the design, manufacture, marketing and sale of Vioxx.

11. Defendant, Louis M. Sherwood, M.D., (hereinafter "Dr. Sherwood"), is a citizen of Pennsylvania, residing at 1241 Forest Hill Drive, Lower Gwynedd, Pennsylvania. Dr. Sherwood is

the former Senior Vice President, Medical and Scientific Affairs in the U.S. Human Health Division of Defendant Merck, a position he held for ten years.

12. While employed by Merck, Dr. Sherwood was responsible for all Medical Services, Academic and Professional Affairs, Clinical Development, and Outcomes Research. Dr. Sherwood also supervised regional Medical Directors across the United States. At Merck, Dr. Sherwood reviewed and supervised clinical trials regarding Vioxx and monitored clinical trials and scientific information regarding Vioxx and competitors of Vioxx. Dr. Sherwood regularly reviewed medical literature pertaining to Vioxx and other COX-2 inhibitors.

13. In his position as Senior Vice President, Medical and Scientific Affairs in the U.S. Human Health Division of Defendant Merck, Dr. Sherwood was principally responsible to protect the safety of consumers, including Plaintiffs herein, by reviewing the clinical trials and the medical literature and then using this information to provide adequate warnings of the risks of Vioxx, including myocardial infarction and stroke.

14. Dr. Sherwood knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe and subjected consumers, including Plaintiffs herein, to the risk of injuries including myocardial infarction and stroke, yet Dr. Sherwood failed to provide adequate warnings regarding such risks.

15. Dr. Sherwood knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe, yet he withheld that information from consumers, including Plaintiffs, while providing false assurances of safety which were provided not only to physicians but directly to consumers.

16. Dr. Sherwood failed to exercise reasonable care as set forth above and thus,

consumers, including Plaintiffs, were subjected to an increased risk of harm of myocardial infarction and stroke.

17. Plaintiffs have been injured as a proximate result of Dr. Sherwood's failure to exercise reasonable care in the design, manufacture, marketing and sale of Vioxx.

18. In his position as Senior Vice President, Medical and Scientific Affairs in the U.S. Human Health Division of Defendant Merck, Dr. Sherwood was responsible for ensuring consumer safety, including Plaintiffs herein, by providing adequate warnings of the risks of Vioxx, including myocardial infarction and stroke. Dr. Sherwood knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe and subjected consumers, including Plaintiffs herein, to the risk of injuries including myocardial infarction and stroke, yet Dr. Sherwood failed to provide adequate warnings regarding such risks.

19. Defendant, David W. Anstice (hereinafter "Mr. Anstice") is a citizen of Pennsylvania, residing at 5280 Militia Hill Road, Plymouth Meeting, Pennsylvania. Mr. Anstice is President of Merck's Human Health Division and has been employed with the company since 1974. From 1997 to 2002, Mr. Anstice was President of the Human Health Division of Defendant Merck. Mr. Anstice is based at the North Wales, Pennsylvania location of Defendant, Merck and is a member of the Management Committee of Defendant Merck.

20. As a member of the Management Committee, Mr. Anstice assists Merck's Chairman, President and Chief Executive Officer in managing business operations and in formulating growth strategies and corporate policies. Mr. Anstice is and was directly responsible for introducing new drugs to the market, including Vioxx.

21. Mr. Anstice, at all relevant times hereto, was responsible for Defendant Merck's

Human Health business in the United States and elsewhere. From 1997 to 2002, he was responsible for Defendant Merck's prescription drug business and the marketing of Merck's pharmaceutical products in the United States. Mr. Anstice is and was responsible to protect the safety of consumers, including Plaintiffs herein, by providing adequate warnings of the risks of Vioxx, including myocardial infarction and stroke.

22. Mr. Anstice knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe and subjected consumers, including Plaintiffs herein, to the risk of injuries including myocardial infarction and stroke, yet Mr. Anstice failed to provide adequate warnings regarding such risks.

23. Mr. Anstice knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe, yet he withheld that information from consumers, including Plaintiffs, while providing false assurances of safety, which were provided not only to physicians but directly to consumers.

24. Mr. Anstice failed to exercise reasonable care as set forth above and thus, consumers, including Plaintiffs, were subjected to an increased risk of harm of myocardial infarction and stroke. Mr. Anstice had undertaken the responsibility of ensuring the safety of Vioxx. Plaintiffs have been injured as a proximate result of Mr. Anstice's failure to exercise reasonable care in the design, manufacture, marketing and sale of Vioxx.

25. Mr. Anstice was responsible to protect the safety of consumers, including Plaintiffs herein, by providing adequate warnings of the risks of Vioxx, including myocardial infarction and stroke.

26. Mr. Anstice knew, or in the reasonable exercise of due care, should have known, that

Vioxx was unsafe and subjected consumers, including Plaintiffs herein, to the risk of injuries including myocardial infarction and stroke, yet Mr. Anstice failed to provide adequate warnings regarding such risks.

27. Defendant Edward M. Scolnick, M.D. (hereinafter "Dr. Scolnick") is currently a citizen of Massachusetts, residing at 1201 Magnolia Drive, Wayland, Middlesex County, MA 01778. Prior to August 2003, however, Dr. Scolnick resided at 811 Wickfield Road, Wynnewood, Montgomery County, PA 19096. Dr. Scolnick was the senior most scientist at Merck from the early 1990's to the date of his retirement in 2003. Dr. Scolnick was President of Merck Research Laboratories and was a member of Merck's Board of Directors. He was a director, officer and shareholder of Merck.

28. At all times relevant hereto, and while he was living in Pennsylvania, Dr. Scolnick was in charge of the scientific development and testing of Vioxx, as well as the development and promulgation of product safety warnings for Vioxx. At all times pertinent hereto, Dr. Scolnick was a primary decision maker in regard to Vioxx. In his position as President of Merck Research Laboratories during the time that Vioxx progressed from the pre-approval process through the time of post-marketing trials, including VIGOR, Dr. Scolnick was responsible to protect the safety of consumers, including the Plaintiffs, by providing adequate warnings of the risks of Vioxx, including myocardial infarction and stroke.

29. Dr. Scolnick knew, or in the reasonable exercise of care, should have known, that Vioxx was unsafe and subjected consumers, including Plaintiffs herein, to the risk of injuries including myocardial infarction and stroke, yet Dr. Scolnick failed to provide adequate warnings regarding such risks.

30. Dr. Scolnick knew, or in the reasonable exercise of due care, should have known, that Vioxx was unsafe, yet he withheld that information from consumers, including Plaintiffs, while providing false assurances of safety, which were provided not only to physicians, but directly to consumers.

31. Dr. Scolnick failed to exercise reasonable care as set forth above and thus, consumers, including Plaintiffs, were subject to an increased risk of harm of myocardial infarction and stroke. Dr. Scolnick had undertaken the responsibility of ensuring and promoting drug safety for consumers of Vioxx, including Plaintiffs herein. Plaintiffs have been injured as a proximate cause of Dr. Scolnick's failure to exercise reasonable care in the design, manufacture, marketing and sale of Vioxx.

32. Merck, Dr. Kim, Dr. Sherwood, Mr. Anstice & Dr. Scolnick are hereinafter collectively referred to as "Defendants."

JURISDICTIONAL STATEMENT

33. This Court has jurisdiction pursuant to 28 U.S.C. §1332. Plaintiff hereby avers that the amount in controversy in the above captioned matter exceeds the jurisdictional limits that said controversy arises between citizens of different states as is required by the aforementioned statute in order to invoke the "Diversity of Citizenship" jurisdiction of this Court. Plaintiff also hereby invokes the pendent jurisdiction of this Court to hear and decide claims arising under state law. This Court also has jurisdiction over Defendants because it is a corporation which is authorized to conduct, and in fact do conduct, substantial business in the Commonwealth of Pennsylvania. These defendants have sufficient minimum contacts with Pennsylvania or otherwise intentionally avails itself of the consumer markets within Pennsylvania through the promotion, sale, marketing and/or

distribution of its products in the Commonwealth to render the exercise of jurisdiction by the Pennsylvania courts permissible under traditional notions of fair play and substantial justice.

FACTUAL ALLEGATIONS

34. At all times relevant and material hereto, defendants have conducted continuous and substantial business in the Commonwealth of Pennsylvania.

35. At all times relevant and material hereto, the defendant Merck acted and gained knowledge itself and by and through its various agents, servants, employees, and/or ostensible agents including the other named defendants in this Complaint.

36. As more particularly pleaded below, plaintiff maintains that the pharmaceutical drug, Vioxx, is defective, dangerous to human health, unfit and unsuitable to be marketed and sold in commerce, and lacked proper warnings as to the dangers associated with its use.

37. At all relevant times, defendants were in the business of developing, researching, selling, distributing, designing, manufacturing, testing, evaluating, licensing, labeling, and/or marketing, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Vioxx.

38. At all relevant times, defendants did in fact develop, research, sell, distribute, design, manufacture, test, evaluate, license, label, and/or market, either directly or indirectly through third parties or related entities, pharmaceutical drugs including Vioxx.

39. Merck obtained FDA approval on Vioxx in approximately May, 1999 and began its distribution and sale throughout the United States in approximately May, 1999. Vioxx is the brand name used by Merck to market and distribute Rofecoxib.

40. Defendants concealed the serious cardiovascular risks associated with Vioxx because

a successful launch of Vioxx was viewed as critical for Merck and safety concerns over hypertension, thrombosis, anemia and/or cardiovascular events would have dramatically impacted Merck's competitive position in the market as compared to its competitor drug Celebrex (Celecoxib), which have been placed into the market by Merck's competitor Pharmacia and Pfizer some three months prior to the launch of Vioxx.

41. Defendants knowingly chose to market this product, despite its knowledge at product launch and its post-marketing data thereafter that use of Vioxx carries significant risk factors. These adverse effects were realized in Adverse Event Reports, in clinical trials where such events were adjudicated by primary investigators with Defendants' assistance, and one or more studies shortly after market launch which shows statistically significant increases in adverse cardiac events among Vioxx users.

42. During the years 2001-2003, the Plaintiff, Mary Bowen, was prescribed, and took as directed, Merck's drug Vioxx for treatment of arthritis / pain symptoms.

43. As a direct and proximate result of the liability-producing conduct of defendants and the defective and unreasonably dangerous condition of its product Vioxx, the Plaintiff Mary Bowen, suffered physical injury and damage, including, but not limited to, a heart attack on or about October 11, 2003.

44. During the years 2001 through 2003, the Plaintiff, Iva Lang, was prescribed, and took as directed, Merck's drug Vioxx for treatment of arthritis / pain symptoms.

45. As a direct and proximate result of the liability-producing conduct of defendants and the defective and unreasonably dangerous condition of its product Vioxx, the Plaintiff Iva Lang suffered physical injury and damage, including, but not limited to, a heart attack on or about October

17, 2003.

46. As a direct and proximate result of defendants' liability-producing conduct and defective product Vioxx: plaintiffs have in the past and will in the future experience physical injuries, pain and suffering, loss of enjoyment of life, lost wages, lost earning capacity, medical expenses, medical monitoring expenses, embarrassment and humiliation, fright and apprehension, emotional distress, and other damages all of which are believed to be permanent.

47. Vioxx is the brand name of Rofecoxib, one of a class of drugs called "prostaglandins," which work to reduce inflammation and pain by providing analgesic and anti-inflammatory benefits to persons with, among other conditions, arthritis and muscle pain. Prostaglandin are COX (cyclooxygenase) inhibitors; COX enzymes metabolize arachidonic acid to produce Prostaglandin.

48. Vioxx is a COX-2 inhibitor, which is designed to produce Prostaglandin as inflammatory sites, and to produce prostacyclin, a vasodilator and an inhibitor of platelet aggregation.

49. Defendants submitted an Application to Market a new Drug for Human Use ("NDA") for Rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for tablets, at doses of 12.5 mg and 25 mg, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-042 by the FDA.

50. Defendants also submitted an Application to Market a New Drug for Human Use ("NDA") for Rofecoxib to the United States Food and Drug Administration ("FDA") on November 23, 1998, for oral suspension, at doses of 12.5 mg/ml and 25 mg/ml, for relief of the signs and

symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea. This application was denoted NDA 21-052 by the FDA.

51. On or about May 20, 1999, the FDA approved NDA 21-042 and NDA 21-052 (hereinafter the "NDA") for Rofecoxib, for relief of the signs and symptoms of osteoarthritis, the management of acute pain, and the treatment of primary dysmenorrhea.

52. At the time the drug was approved by the FDA the labeling for Rofecoxib stated, in the section entitled "Special Studies - Upper Endoscopy in Patients with Osteoarthritis," "Treatment with VIOXX 25 mg daily or 50 mg daily was associated with a significantly lower percentage of patients with endoscopic gastroduodenal ulcers than treatment with ibuprofen 2400 mg daily. However, the studies cannot rule out at least some increase in the rate of endoscopic gastroduodenal ulcers when comparing VIOXX to placebo."

53. The "Warnings" section of the labeling for Rofecoxib, at the time the drug was approved by the FDA, contains a section, "Gastrointestinal (GI) Effects - Risk of GI Ulceration, Bleeding, and Perforation."

54. Defendants submitted sNDA-007 with the goal of establishing a gastrointestinal ("GI") safety claim for Rofecoxib. In conjunction with the sNDA, Defendant Merck performed the Vioxx GI Outcomes Research (VIGOR) Protocol, No. 088-04, entitled "A Double-Blind, Randomized, Stratified, Parallel-Group Study to Assess the Incidence of PUBs During Chronic Treatment With MK-0966 or Naproxyn in Patients With Rheumatoid Arthritis: U.S, Cohort." The VIGOR study was performed from January 6, 1999 through March 17, 2000.

55. The objectives of the VIGOR study were to (1) "determine the relative risk of confirmed PUB (Perforation, Ulcers, Bleeding) in patients taking MD-0966 50 mg daily compared

to patients in the group taking Naproxyn 1000 mg/day," and (2) "study the safety and tolerability of MK-0966 in patients with rheumatoid arthritis."

56. In industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck is a member and corporate sponsor, in June of 2000, it was shown that Vioxx use resulted in a statistically significant increase in hypertension and stroke. Not only did Merck do nothing to further accurately publish these studies, or warn consumers, but it denied the results with respect to hypertension in the official publication of the American Pharmaceutical Association, PHARMACY TODAY, *Spin War Aside, Lessons Emerge From COX-2 Trials, in August 2000, page 3.*

57. Defendants continued to deny the ill health effects associated with Vioxx while at the same time reaping profits obtained through its non-disclosure and concealment. Defendants engaged in a massive advertising and sampling program and gained continued increases in the market share, which enhanced their financial stability to the detriment of its consumers. As a result of Defendants' scheme, Merck reaped more than $2 billion in profit in the year 2000 alone, and appropriated approximately 23 percent share of the market and the other named defendants reaped substantial financial compensation in bonus, salary, stock options and more.

58. Merck continued to profit from its scheme by withholding information from Plaintiffs, the consuming public, and the health care industry. For example, in November of 2000, Defendants caused the publication of a study in the NEW ENGLAND JOURNAL OF MEDICINE in which it knowingly downplayed and/or withheld the severity of cardiovascular risks associated with Vioxx consumption over Naproxyn consumption.

59. On or about August 29, 2001, the JOURNAL OF THE AMERICAN MEDICAL

ASSOCIATION (JAMA) published a peer-reviewed human epidemiologic study by the Cleveland Clinic Foundation, Cleveland, Ohio, Dr. D. Mukhisjee, et al., showing what Defendants had concealed that the relative risk of developing a "confirmed adjudicated thrombotic cardiovascular event" (defined in the article as "myocardial infarction, unstable angina, cardiac thrombus, resuscitated cardiac arrest, sudden or unexplained death, ischemic stroke, and transient ischemic attacks") among Vioxx users in Defendants' trials, including VIGOR, at 95% confidence interval ranged from 2.2 for event-free survival analysis, 2.38 compared to Naproxyn users, and 4.89 for developing serious cardiovascular events among aspirin-indicated patients. *See* Mukhisjee, D., et al., *Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors*, J.A.M.A. 286:8, 954-959, Aug. 22/29, 2001. In addition, the annualized myocardial infarction rates for Vioxx users compared to placebo revealed a statistically significant increase among Vioxx users.

60. In the JAMA study, the authors stated that "by decreasing PG12 production [Vioxx] may tip the natural balance between prothrombotic thromboxane A2 and antithrombotic PG12, potentially leading to an increase in thrombotic cardiovascular events." *Id.* at 957. In a follow-up peer reviewed study reported in the Journal of the American College of Cardiology on or about February 6, 2002, Dr. Richard J. Bing conducted scientific testing and confirmed that the Cox-2 inhibitor "tips the balance of prostacyclin/thromboxane in favor of thromboxane, leading to increased vascular and thrombotic events." Bing, R., & Lomnicka, M., *Why Do Cyclo-Oxygenase-2 Inhibitors Cause Cardiovascular Events?*, J.A.C.C., 39:3, Feb. 6, 2002. This is further supported by studies completed at the University of Pennsylvania. Cheng, Y., et al., *Role of Prostacyclin in the Cardiovascular Response to Thromboxanne* A2, JOURNAL OF SCIENCE, v. 296:539-541, Apr. 19, 2002.

61. On September 17, 2001, Thomas W, Abrams, R.Ph., MBA, Director of the FDA Division of Drug Marketing, Advertising, and Communications, issued a "Warning Letter" to Raymond V. Gilmartin, President and CEO of Merck, relating to "promotional activities and materials for the marketing of Vioxx (Rofecoxib) tablets."

62. The Warning Letter stated that Defendant Merck had "engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, and thus, misrepresents the safety profile for Vioxx." The letter further states:

> Specifically, your promotional campaign discounts the fact that in the VIGOR study, patients on Vioxx were observed to have a four to five fold increase in myocardial infarction (MIs) compared to patients on the comparator non-steroidal anti-inflammatory drug (NSAID), Naproxyn (Naproxyn).

63. The eight (8) page Warning Letter outlines, in detail, the conduct of Defendant Merck that supports the FDA's issuance of the Warning Letter, and makes the following **"Conclusions and Requested Actions:"**

> The promotional activities and materials described above minimized the potentially serious Cardiovascular findings that were observed in the VIGOR study, minimized the Vioxx / Coumadin drug interaction, omit crucial risk information associated with Vioxx therapy, contain unsubstantiated comparative claims, and promote unapproved uses. On December 16, 1999, we also objected to your dissemination of promotional materials for Vioxx that misrepresented Vioxx's safety profile, contained unsubstantiated comparative claims, and lacked fair balance.
>
> Due to the seriousness of these violations, and the fact that your violative promotion of Vioxx has continued despite our prior written notification regarding similar violations, we request that you provide a detailed response to the issues raised in this Warning Letter on or before October 1, 2001.

> This response should contain an action plan that includes a comprehensive plan to disseminate corrective messages about the issues discussed in this letter to the audiences that received theses misleading messages. This corrective action plan should also include:
>
> Immediately ceasing all violative promotional activities, and the dissemination of violative promotional materials for Vioxx.
>
> Issuing a "Dear healthcare provider" letter to correct false or misleading impressions and information. This proposed letter should be submitted to us for review prior to its release. After agreement is reached on the content and audience, the letter should be disseminated by direct mail to all healthcare providers who were, or may have been exposed to the violative promotion.
>
> A written statement of your intent to comply with "1" and "2" above.

64. On April 11, 2002, the FDA approved a supplemental application for the use of Vioxx (Rofecoxib) for rheumatoid arthritis, adding this indication to the previously approved indications for osteoarthritis and pain. The FDA also approved new labeling, a "Dear Doctor" letter, and a new patient package insert. The labeling and the "Dear Doctor" letter contained information concerning the results of the VIGOR study.

65. The revised labeling further states that the administration of Vioxx 50 mg, was associated with a higher incidence of gastrointestinal symptoms as follows:

> **Clinical Studies in OA and RA with Vioxx 50 mg (Twice the highest dose recommended for chronic use)**
>
> In OA and RA clinical trials which contained VIOXX 12.5 or 25 mg as well as VIOXX 50 mg, VIOXX 50 mg OD was associated with a higher incidence of gastrointestinal symptoms (abdominal pain, epigastric pain, heartburn, nausea and vomiting), lower extremity edema, hypertension, serious* adverse experiences and discontinuation due to clinical adverse experiences compared to the recommended chronic doses of 12.5 and 25 mg [See DOSAGE AND ADMINISTRATION].

66. Further, the "Dear Doctor" letter approved in conjunction with the revisions to the Vioxx labeling, outlines the changes to the Vioxx labeling.

67. The revised "Patient Information" sheet does not add any information about the results of the VIGOR study."

68. The "Patient Information" sheet is the only written document that is provided to a patient for whom Vioxx is prescribed.

69. Both the initial labeling and the revised labeling are ineffective because they do not properly advise physicians and patients of the potential gastrointestinal and prothrombotic side effects of Vioxx.

70. Despite knowledge of the ineffectiveness of the warnings, and despite knowledge that Vioxx may cause serious side effects, Defendants have concealed and/or downplayed the dangers associated with Vioxx, and continues to market the drug in the United Stats and abroad. In its 2001 Annual Report, for example, Merck states:

> The Company also notes that a number of the federal and state lawsuits, involving individual claims as well as purported class actions, have been filed against the Company with respect to Vioxx . . . The lawsuits include allegations regarding gastrointestinal bleeding and cardiovascular events. The Company believes that these lawsuits are completely without merit and will vigorously defend them.

71. Further, in its January 23, 2001 8-K filing with the Securities and Exchange Commission, Merck fails to mention the cardiac and cardiothrombotic findings of the VIGOR study:

> "Our results reflect the strength of our growth strategy," Mr. Gilmartin said. "Our five key products, **VIOXX**, ZOCOR, COZAAR/HYZAAR*, FOSAMAX and SINGULAR, drove Merck's performance for the year created a powerful platform for growth." These products accounted for 57% of Merck's worldwide human health sales for 2000 and 61% for the fourth quarter.

> "Each of the five medicines offers unique competitive advantages, " Mr. Gilmartin said. **VIOXX**, a once-a-day medicine, is the only COX-2 indicated in the United States both for osteoarthritis and acute pain. Since its extraordinarily successful 1999 launch, **VIOXX** has become the world's fastest growing branded prescription arthritis medicine, and it is already Merck's second largest-selling medicine. In the United States, **VIOXX** now accounts for approximately 50 percent of new prescriptions in the COX-2 class, despite being second to market in this class in the United States. **VIOXX** achieved $2.2 billion in sales for the full year 2000, with $700 million in the fourth quarter.
>
> A Food and Drug Administration (FDA) Advisory Committee meeting is scheduled for Feb. 8 to review labeling changes Merck has requested based on the strong results of the VIGOR Study. This 8,000-patient gastrointestinal outcomes research study, in which **VIOXX** reduced the risk of serious gastrointestinal complications by half compared to the NSAID Naproxyn, was published in November in THE NEW ENGLAND JOURNAL OF MEDICINE. Another study, presented in November, showed that **VIOXX** significantly reduced moderate-to-severe acute pain after dental surgery to a greater degree compared to codeine combined with acetaminophen.

72. Despite the foregoing, Defendants continued to represent to consumers that Vioxx is safe, and that any cardiovascular and/or cardiothrombotic side effects are not associated with the drug. Defendants have downplayed any potential gastrointestinal side effects of the drug, promoting it is safer and more efficacious than other medications approved for treatment of similar conditions.

73. At all times relevant to this litigation, Merck had a significant market share based upon claims of Vioxx's efficacy, a very aggressive marketing program which included financial incentives to sales teams, infusion of some 700 new sales representatives and a massive direct-to-consumer advertising and physician sampling program.

74. As a result of such marketing, Vioxx gained a significant market share in competition with Celebrex that Merck would not have gained if Merck had not suppressed information about

Vioxx and/or made false representations of Vioxx's superiority and efficacy.

75. If Defendants had not engaged in this conduct, prescribers such as Plaintiff's prescriber would not have prescribed Vioxx in patients, such as the Plaintiffs, would have switched from Vioxx to safer products or would have refrained wholly from any use of Vioxx.

76. From approximately 1999 through the present, Defendants continued to engage in a common scheme in marketing, distributing and/or selling Vioxx under the vise that it was safe and efficacious for persons such as Plaintiffs before, during and after Plaintiffs experienced their confirmed injuries.

77. Plaintiffs allege that the suppression of this information constituted a common scheme by Defendants to conceal material information from plaintiffs.

78. Plaintiffs allege that the marketing strategies, including without limitation, the detail and sampling program and direct-to-consumer advertising, of the Defendants targeted plaintiffs to induce plaintiffs to purchase Vioxx. At the time that Merck distributed, manufactured and marketed Vioxx, defendants intended that plaintiffs would reply on the marketing, advertising and product information propounded by Defendants.

79. The actions of Defendants in failing to warn of the clear and present danger posed to others by the use of its drug Vioxx in suppressing evidence relating to this danger, and in making deliberate and misleading misrepresentations of fact to minimize the danger or to mislead prescribers and patients as to the true risk, constitutes such clear, blatant and outrageous conduct as to warrant the imposition of exemplary damages against the Defendants.

COUNT I
NEGLIGENCE

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

80. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

81. Defendants, directly or indirectly negligently manufactured, designed, tested, labeled, packaged, distributed, promoted, marketed, advertised, or sold Vioxx (Rofecoxib) in the stream of commerce, when it knew, or in the exercise of ordinary care, should have known that Vioxx posed a significant risk to Plaintiffs' health and well-being, which risk was not known to Plaintiffs or their prescriber.

82. Despite the numerous studies and clinical trials showing an increased risk of cardiovascular side effects, Defendants, Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D., and Edward Scolnick, M.D., continued to represent to consumers that Vioxx was safe and that any cardiovascular and/or cardiothrombotic side effects were not associated with the drug. The Defendants also downplayed potential cardiovascular side effects of the drug, promoting it as safer and more efficacious than other medications approved for treatment of similar conditions.

83. Defendants knew, or in the exercise of reasonable care, should have known, that the aforesaid product was of such a nature that if not properly manufactured, labeled, tested, and inspected before sold, the product was likely to cause injury to the product's user.

84. At all times material hereto, Defendants had a duty to plaintiffs to exercise reasonable care in the design, testing, labeling, packaging, distribution, promotion, marketing, advertisement,

sampling or sale of Vioxx.

85. Defendants breached its duty and was negligent in its actions, misrepresentations, and omissions toward Plaintiffs in that the Defendants:

a. failed to use reasonable care to design an arthritis drug (Vioxx) that was safe for its intended and foreseeable uses, not defective, and not unreasonably dangerous;

b. failed to use reasonable care in designing and manufacturing an Vioxx so as to make it safe for its intended uses, not defective, and not unreasonably dangerous;

c. failed to use reasonable care to adequately warn foreseeable users such as plaintiffs of the dangers of using Vioxx, including, but not limited to adverse cardiac events;

d. failed to use reasonable care to make reasonable tests, inspections, drug trials, and/or evaluations necessary to discover such defects and unreasonably dangerous conditions associated with defendants' Vioxx;

e. failed to comply with and/or to use reasonable care to comply with standards of care including accepted industry standards, FDA recommendations, government regulations, statutes, in the design, manufacture, affixing of warnings, and otherwise production and distribution of defendants' Vioxx;

f. failed to use reasonable care to timely remove and/or recall from the market, retrofit, and/or otherwise prevent the continued contact of plaintiffs or persons like plaintiffs with such defects and unreasonably dangerous

conditions of Vioxx;

g. failed to use reasonable care to investigate and/or use known and/or knowable reasonable alternative designs, manufacturing processes, and/or materials for Vioxx;

h. failed to use reasonable care to warn plaintiffs of dangers known and/or reasonably suspected to Defendants to be associated with Vioxx;

i. failed to use reasonable care to make Vioxx safe;

j. failed to timely use reasonable care to discover the dangerous conditions or character of defendants' Vioxx:

i. failed to use due care in the design, testing and manufacturing of Vioxx so as to prevent the aforementioned risks, including myocardial infarction and stroke, to individuals when Vioxx was used as a medication for arthritis and other pain;

ii. failed to issue proper warnings regarding all possible adverse side effects associated with the use of Vioxx and the comparative severity and duration of such adverse effects, despite the fact the Defendants knew, or should have known that numerous case reports, adverse event reports, and other data that associated Vioxx with myocardial infarction and stroke;

k. failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Vioxx;

l. failed to provide adequate training and information to medical care providers

for the appropriate use of Vioxx;

m. failed to warn Plaintiffs and healthcare providers, prior to actively encouraging and promoting the sale of Vioxx, either directly, or indirectly, orally, in writing, or other media about the following:

i. The adverse side effects associated with the use of Vioxx, including, but not limited to myocardial infarction and stroke; and,

ii. The possibility of becoming disabled as a result of using Vioxx, and

n. failed to timely develop and implement a safer, alternative design of Vioxx, which would meet the same need without the known risks associated with Vioxx and which would not have made the product too expensive to maintain its utility.

86. Despite the fact that Defendants knew, or reasonably should have known, that Vioxx caused unreasonable and dangerous side effects, including, but not limited to myocardial infarction and stroke, which many users would be unable to remedy by any means, Defendants continued to promote and market Vioxx to consumers, including Plaintiffs, without warning Plaintiffs of these side effects, when safer, alternative pharmaceutical agents for the treatment of arthritis and muscular pain symptoms were available.

87. Defendants knew or should have known that Vioxx caused unreasonably dangerous risks and serious side effects, of which Plaintiffs would not be aware. Defendants nevertheless advertised, marketed, sold and distributed the drug knowing that there were safer methods and products.

88. As a direct and proximate result of the negligence and breach of Defendants, Plaintiffs

sustained serious injury. Defendants owed a duty to Plaintiffs to use reasonable care in its actions. Defendants' failure to use reasonable care proximately caused Plaintiffs' injuries.

89. As a direct and proximate result of Defendants's negligence, plaintiffs were harmed as aforesaid.

COUNT II
NEGLIGENCE *PER SE*

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

90. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

91. At all times mentioned herein, Defendants had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, distribution, marketing, labeling, packaging preparation for use, sale and warning of the risks and dangers of the aforementioned product.

92. At all times herein mentioned, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, *et seq*., related amendments and codes and federal regulations provided thereunder, and other applicable laws, statutes and regulations.

93. Plaintiff, as a purchaser and consumer of the product, is within the class of persons the statutes and regulations described above are designed to protect, and the injuries alleged herein are the type of harm these statutes are designed to prevent.

94. Defendants' acts constitute an adulteration and/or misunderstanding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and constitutes a breach of duty subjecting Defendants to civil liability for all damages arising therefrom, under theories of negligence *per se.*

95. Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs, making Defendants negligent *per se*: (a) the Labeling lacked adequate information on the use of the drug Vioxx; (b) the labeling failed to provide adequate warnings of severe and disabling medical conditions as soon as there was reasonable evidence of their association with the drug; (c) there was inadequate information for patients for the safe and effective use of Defendants' drug; (d) there was inadequate information regarding special care to be exercised by the doctor for safe and effective use of Defendants' drug; and (e) the labeling was misleading and promotional.

96. As a result of the violations of the statutes described above, Plaintiff suffered serious injuries and damages, as alleged herein.

COUNT III
STRICT LIABILITY
(Design Defect)

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

97. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

98. Plaintiffs ingested Vioxx, a medication that was either manufactured, distributed, sold, prescribed and/or otherwise put into the stream of commerce by the Defendant Merck. The defective condition of Vioxx rendered it unreasonably dangerous, and that said Vioxx was in this defective condition at the time it left the hands of the Defendant.

99. The Defendants engaged in the manufacture, distribution, sale and/or prescription of pharmaceutical medications. Vioxx, without substantial change in the condition in which it was sold, was a proximate cause of Plaintiffs' injuries.

100. Plaintiffs were unaware of the significant hazards and defects in the Vioxx medication. Therefore, the Vioxx medication was unreasonably dangerous in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the periods the Plaintiffs were taking Vioxx, the medication was being utilized in a manner which was intended by Defendants.

101. Vioxx was defectively designed because the foreseeable risks exceeded the benefits associated with the design and formulation.

102. Additionally, Vioxx is defective due to inadequate clinical trials, testing, study, and inadequate reporting regarding the results of same.

103. Defendants designed, manufactured, and/or placed into the stream of commerce the product, which reached Plaintiffs in the same or substantially the same condition in which it was sold. Upon purchase by Plaintiffs, the product in question was represented to be safe and free from latent defects.

104. Defendants are strictly liable to Plaintiffs for designing, manufacturing, and placing into the stream of commerce the product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects which were a producing cause of the occurrence in question.

105. The product in question was defectively marketed by Defendants with respect to its failure to warn, adequately warn, or instruct in the safe use of the product and such defect was a producing cause of the occurrence in question.

106. Defendants knew, or in the exercise of ordinary care should have known, that the product was defective and unreasonably dangerous to those persons likely to use the product for the

purpose and in the manner for which it was intended to be used. Defendants were negligent in the particulars set forth in this and the preceding paragraphs and such negligence was a proximate cause of the occurrence in question.

107. Defendants owed Plaintiffs the duty of reasonable care when they tested, designed, manufacture, and marketed the product in question. Defendants violated their duty and were negligent in the particulars set forth herein.

108. Defendant Merck is also strictly liable under Section 402(B) of the Restatement (Second) of Torts in misrepresenting to the public that its product was safe and without defect, which statement and representation was false and involved a material fact concerning the character or quality of the product in question, and upon which misrepresentations the consumer constructively relied, and which constituted a producing cause of the injuries at issue.

109. At all relevant times, defendants' Vioxx was defective and unreasonably dangerous under section 402(A) Restatement (Second) of Torts 402, and the New Jersey Products Liability Act and/or New York, and or applicable Pennsylvania or Minnesota laws and statutes.

110. Further, each of the above and foregoing acts or omissions of Defendants were more than momentary thoughtlessness, inadvertence, or error of judgment. Such acts or omissions constituted such an entire want of care as to establish that the acts or omissions were the result of actual conscious indifference to the rights, safety, or welfare of the person or persons affected.

111. As a direct and proximate result of defendants' defective and unreasonably dangerous product and its failure to warn plaintiffs and others like them of same, plaintiffs were harmed as aforesaid.

COUNT IV
STRICT LIABILITY
(Failure to Warn)

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

112. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

113. Defendants, as manufacturers and suppliers of Vioxx, failed to provide proper warnings regarding all possible adverse side effects regarding the use of Vioxx, as well as the severity and duration of such adverse effects.

114. Defendants failed to perform adequate testing that would have shown that Vioxx possessed serious potential side effects with respect to which full warnings were needed.

115. Defendants, manufacturer and suppliers of Vioxx, failed to provide adequate post-marketing warning and instruction because, after Defendants knew or should have known of the risk of injury and deaths from Vioxx, Defendants failed to provide adequate warnings and continued to aggressively promote Vioxx.

116. As a direct and proximate result of defendants' defective and unreasonably dangerous product and its failure to warn plaintiffs and others like them of same, plaintiffs were harmed as aforesaid.

COUNT V
NEGLIGENT FAILURE TO WARN

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

117. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

118. At all relevant times, defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Vioxx, and in the course of same, directly advertised or marketed the product of FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Vioxx.

119. At all relevant times, Vioxx was under the exclusive control of the Defendants as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Vioxx, dangerous drug-drug interactions and food-drug interactions, and the comparative severity, duration and the extent of the risk of injury with such use.

120. At all relevant times, defendants has failed to timely and reasonably warn of material facts regarding the safety and efficacy of Vioxx so that no medical care provider would have prescribed, or no consumer would have used, Vioxx had those facts been made known to such providers and consumers.

121. At all relevant times, defendants failed to perform or otherwise facilitate adequate testing in that such testing would have shown that Vioxx posed serious and potentially life-threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to medical care providers, the FDA and the public, including the Plaintiffs.

122. At all relevant times, Vioxx, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warning

and/or instruction because, after Defendants knew or should have known of the risk of serious and potentially life-threatening side effects and complications from the use of Vioxx, Defendants failed to provide adequate warnings to medical care providers, the FDA and the consuming public, including Plaintiffs, and continued to promote Vioxx aggressively.

123. As a direct and proximate result of defendants' defective and unreasonably dangerous product and its failure to warn plaintiffs and others like them of same, plaintiffs were harmed as aforesaid.

COUNT VI
BREACH OF EXPRESS WARRANTY

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

124. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

125. Defendants manufactured, sold, distributed, marketed, and/or promoted Vioxx that was ingested by Plaintiffs.

126. The Vioxx ingested by the Plaintiffs was expected to, and did reach her/him without a substantial change in condition.

127. Merck, its agents and employees, including, but not limited to defendants, Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D., and Edward Scolnick, M.D., in manufacturing, selling, distributing, supplying, marketing and/or promoting Vioxx, impliedly warranted that Vioxx was not unreasonably dangerous, and instead warranted that it was of merchantable quality, reasonably fit and safe for its intended, reasonably foreseeable use as a medication for arthritis and muscular pain.

128. Merck, its agents and employees, including, but not limited to defendants, Peter S. Kim,Ph.D., David Anstice, Louis Sherwood, M.D., and Edward Scolnick, M.D., breached these warranties in that Vioxx was not of merchantable quality, was not fit for its intended and reasonably foreseeable use, and was unreasonably dangerous in light of the risk of side effects associated with its use, including, but not limited to myocardial infarction and stroke, and in light of other risks of serious injuries and adverse side effects to foreseeable users.

129. Merck, its agents and employees, including, but not limited to defendants, Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D., and Edward Scolnick, M.D., also failed to provide adequate warnings for Vioxx, rendering it unreasonably dangerous and unfit for the intended and/or reasonably foreseeable purposes of use, in breach of this warranty.

130. Plaintiffs justifiably and detrimentally relied upon the warranties and representations of defendants in the purchase and use of Vioxx.

131. Vioxx, as purchased and ingested by Plaintiffs, was formulated, manufactured, marketed, packaged, labeled by Defendants with implied warranties of merchantability and of fitness for its intended purpose, without risk of permanent damage to the purchaser's and/or consumer's body and health. Defendants were sellers of, and merchant of Vioxx.

132. Plaintiffs relied upon defendants' implied warranties and upon the Defendants' skill and judgment, in purchasing and ingesting Vioxx.

133. Defendants breached these implied warranties to Plaintiffs in violation of relevant provisions of the applicable Uniform Commercial Code (a) by manufacturing, marketing, packaging, labeling, and selling products to Plaintiffs, with the risk of injuries, including without limitation, strokes and cardiovascular injury, without warning or disclosure thereof by package and label of such

risk to Plaintiffs or their physicians or pharmacists, and/or without so modifying or excluding such implied warranties; (b) by manufacturing, marketing, packaging, labeling and selling to Plaintiffs the product Vioxx, which failed to control Plaintiffs' arthritis and pain and/or suppress Plaintiffs' pain in a safe manner and without injuries, including, without limitation, myocardial infarction and/or stroke and (c) by manufacturing, marketing, packaging, labeling, and selling to Plaintiffs, Vioxx, which caused Plaintiffs serious physical injury and pain and suffering attendant economic loss.

134. As a proximate result of Defendants' breach of implied warranties, Plaintiffs have incurred and will continue to incur: serious physical injury, pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical and hospital expenses and other expenses related to the diagnosis and treatment thereof, for which Defendants are liable.

135. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiffs ingested Vioxx and suffered serious and permanent injuries, including, in some cases, death. As a further direct and proximate result of the acts and omissions of Defendants, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental anguish, and has been deprived of their ordinary pursuits and enjoyments of life.

136. As a direct and proximate result of defendant's defective and unreasonably dangerous Vioxx and its breach express warranty, plaintiffs were harmed as aforesaid.

COUNT VII
BREACH OF EXPRESS WARRANTY

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

137. The Plaintiffs hereby incorporate by reference all other paragraphs of this Complaint as if fully set forth herein, and further allege as follows:

138. Defendants manufactured, sold, distributed, marketed, and/or promoted Vioxx, which was used by Plaintiffs, and this drug was expected to, and did reach Plaintiffs without a substantial change in condition.

139. Merck its agents and employees, including but not limited to Defendants, Peter S. Kim, Ph.D., David Anstice, Louise Sherwood, M.D. and Edward Scolnick, M.D., in manufacturing, selling, distributing, supplying, marketing and/or promoting the drug Vioxx, expressly warranted that the drug was safe and effective as a medication for arthritis and muscular pain.

140. Merck, its agents and employees, including but not limited to Defendants, Peter S. Kim, Ph.D., David Anstice, Louise Sherwood, M.D. and Edward Scolnick, M.D., breached this warranty in that Vioxx was not safe and effective for its intended, reasonably foreseeable use as a medication for arthritis and muscular pain because of the risk of serious cardiovascular side effects associated with its use and in light of other risks of serious injuries to foreseeable users.

141. Defendants failed to provide adequate warnings for Vioxx, rendering it unreasonably dangerous and unfit for the intended, reasonably foreseeable purposes for which it is used, in breach of warranty.

142. Plaintiffs, justifiably and detrimentally, relied upon the warranties and representations of the Defendants in the purchase and use of the product.

143. As a direct and proximate result of the acts and omissions of the Defendants, Plaintiffs suffered serious and permanent injuries, including, in some cases, death. As a further direct and proximate result of the acts and omissions of Defendants, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental anguish, and have been deprived of their ordinary pursuits and enjoyments of life.

144. Defendants through a direct-to-consumer advertising campaign, affirmation of fact and promises relating to their products to the FDA, prescribing physicians, and the general public, including the Plaintiffs herein, expressly warranted that their product, Vioxx, was effective and safe for its intended use.

145. These warranties came in the form of: (a) publicly-made written and verbal assurances of safety and efficacy by Merck, its agents, and employees, including but not limited to Defendants, Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D., including but not limited to statements of clinical data that purported to report the incidence of adverse events experienced for the product Vioxx, but which in fact grossly understated such incidence; and (b) advertisements the sole purpose of which was to create demand for Defendants product, Vioxx, but which failed to warn of the risks inherent to ingestion of Defendants' product, Vioxx or the indications thereof.

146. At the time of the making of these express warranties, Defendants had knowledge or had reason to know or in the exercise of reasonable care would have known of the purpose for which Vioxx was to be used and warranted same to be in all respects safe, effective and proper for such purpose.

147. Merck, its agents and employees of Defendant, including but not limited to

Defendants, Peter S. Kim, Ph.D., David Anstice, Louise Sherwood, M.D. and Edward Scolnick, M.D., themselves drafted the documents and/or made the statements upon which these express warranty claims are based, in so doing, defined the terms of those warranties.

148. Vioxx did not conform to these express representations in that it was neither safe nor effective as a pain reliever, and it produced serious side effects, including, but not limited to, life threatening injuries such as myocardial infarction and stroke.

149. As such, the Defendants' pain reliever product, Vioxx, was neither in conformity to the promises, descriptions or affirmations of fact made of this drug by Defendants nor adequately contained, packaged, labeled, or fit for the ordinary purposes for which such product was to be used.

150. Defendants breached express warranties to Plaintiffs in violation of the relevant provisions of the applicable Uniform Commercial Code: (a) by manufacturing, marketing, labeling, and selling a pharmaceutical product to Plaintiffs in such a way that misstated the risk of injuries, including, without limitation, strokes and myocardial infarction, without warning or disclosing such risk to Plaintiffs or their physician or pharmacist, and/or without so modifying or excluding such erroneous express warranties; (b) by manufacturing, marketing, packaging, labeling, and selling to Plaintiffs Vioxx, and failing to provide a safe pain reliever that did not cause injuries, including, without limitation, strokes and myocardial infarction; and (c) by manufacturing, marketing, packaging, labeling, and selling to Plaintiffs the product Vioxx causing Plaintiffs serious physical injury and pain and suffering.

151. As a proximate result of all Defendants' breach of express warranties, Plaintiffs have incurred and will continue to incur: serious physical injury, pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital, surgical expenses and

other expenses related to diagnosis and treatment thereof, for which Defendants is liable.

As a direct and proximate result of defendant's defective and unreasonably dangerous Vioxx and its breach express warranty, plaintiffs were harmed as aforesaid.

COUNT VIII
MISREPRESENTATION AND SUPPRESSION BY DEFENDANT

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

152. Plaintiffs restate each and every preceding paragraphs as though set forth fully at length herein.

153. Defendant misrepresented to Plaintiffs and the health care industry the safety and effectiveness of Vioxx and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Vioxx.

154. Defendant made misrepresentations and actively concealed adverse information at a time when the Defendant knew, or should have known, that Vioxx had defects, dangers, and characteristics that were other than that what the Defendant had represented to Plaintiffs and the health care industry generally. Specifically, Defendant misrepresented to and/or actively concealed from Plaintiffs, the health care industry and consuming public that:

a. Vioxx had statistically significant increases in cardiovascular side effects, including with limitation thrombosis, myocardial infarction and sudden onset death, as identified herein which could result in serious injury or death;

b. There had been insufficient and/or company-spun studies regarding the safety and efficacy of Vioxx before and after its product launch;

c. Vioxx was not fully and adequately tested for the cardiovascular side effects at issue herein;

d. Other testing and studies showed the risk of or actual serious adverse risks; and/or that

e. There was a greatly increased risk of such cardiovascular events and death; there was a confirmed mechanism by which these thrombotic or cardiovascular events occurred as reported in the scientific literature.

155. The misrepresentations of and/or active concealment alleged were perpetuated directly and/or indirectly by defendant.

156. Defendant knew or should have known that these representations were false and made the representations with the intent or purpose that Plaintiffs would rely on them, leading to the use of Vioxx.

157. At the time of Defendant's fraudulent misrepresentations, Plaintiffs were unaware of the falsity of the statements being made and believed them to be true. Plaintiffs had no knowledge of the information concealed and/or suppressed by Defendant.

158. Plaintiffs justifiably relied on and/or was induced by the misrepresentation and/or active concealment and relied on the absence of safety information which the Defendant did suppress, conceal or failed to disclose to Plaintiffs' detriment.

159. Defendant had a post-sale duty to warn Plaintiffs and the public about the potential risks and complications associated with Vioxx in a timely manner.

160. The misrepresentations and active fraudulent concealment by the Defendant constitutes a continuing tort against Plaintiffs, whom ingested Vioxx.

161. Defendant made the misrepresentations and actively concealed information about the defects and dangers of Vioxx with the intention and specific desire that Plaintiffs' health care professionals and the consuming public would rely on such or the absence of information in selecting

Vioxx as treatment.

162. As a direct and proximate result of the fraudulent acts and omissions, suppression and misrepresentation of Defendant, Plaintiffs suffered injuries and damages.

COUNT IX
FRAUD AND MISREPRESENTATION

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

163. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

164. Defendant fraudulently, intentionally, wilfully and wantonly, purposefully, knowingly, recklessly, negligently and/or in fact materially misrepresented both affirmatively and by omission that its Vioxx was of good quality, non-defective, safe for its intended use, merchantable, and fit for its particular purposes.

165. Defendant intended, knew, and/or should have known that plaintiffs would be induced, by the aforesaid misrepresentations, to use defendant's Vioxx.

166. In using defendant's Vioxx, plaintiffs justifiably relied on defendant's representations that its Vioxx was of good quality, non-defective, safe for its intended use, merchantable, and fit for its particular purposes.

167. Defendant's Vioxx was, in fact, defective and unreasonably dangerous, as recited above.

168. In justifiable and detrimental reliance on the truth of Defendants' representations about the safety of Vioxx, Plaintiffs purchased the product and used the product in the manner and for the purpose intended as represented and instructed by Defendants.

169. The representations, misrepresentations, acts and omissions made by Defendants deprived the Plaintiffs and their physicians and other foreseeable users of Vioxx of the opportunity of free or knowing choice as to whether or not to expose themselves to the aforementioned dangers of ingesting Vioxx.

170. As a direct and proximate result of Plaintiffs' lack of awareness of the dangers of Vioxx, caused by the fraudulent acts and omissions of the Defendants, Plaintiffs ingested Vioxx and suffered serious and permanent injuries. As a further direct and proximate result of the acts and omissions of Defendants, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental anguish, and have been deprived of their ordinary pursuits and enjoyments of life.

171. As a direct and proximate result of defendant's defective and unreasonably dangerous Vioxx as well as its affirmative misrepresentations and omissions, plaintiffs were harmed as aforesaid.

COUNT X
NEGLIGENT MISREPRESENTATION

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

172. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

173. Defendants, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing its statements to be true to Plaintiffs, other patients, and the medical and psychiatric communities.

174. Defendants, through their misrepresentations, intended to induce justifiable reliance

by Plaintiffs, other patients, and the medical and psychiatric communities.

175. Defendants, through their marketing campaign and communications with treating physicians, was in a relationship so close to that of Plaintiffs and other patients that it approaches and resembles privity.

176. Defendants owed a duty to the medical community, Plaintiffs, and other consumers, to conduct appropriate and adequate studies and tests for all its products, including Vioxx, and to provide appropriate and adequate information and warnings.

177. Defendants failed to conduct appropriate or adequate studies for Vioxx.

178. Defendants failed to exercise reasonable care by failing to conduct studies and tests of Vioxx.

179. As a direct and proximate result of Defendants' negligent misrepresentations. Plaintiffs were harmed as aforesaid.

COUNT XI
VIOLATION OF UNFAIR TRADE PRACTICE/CONSUMER PROTECTION LAWS

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

180. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

181. At all relevant times, defendants knew or should have known that the use of Vioxx causes serious and life-threatening injuries but failed to warn the public, including Plaintiffs, of same.

182. At all relevant times, defendants made untrue, deceptive or misleading representations of material facts to and omitted and/or concealed material facts from plaintiffs in product packaging,

labeling, medical advertising, direct-to-consumer advertising, promotional campaigns and materials, among other ways, regarding the safety and use of Vioxx. Moreover, defendants downplayed and/or understated the serious nature of the risks associated with Vioxx in order to increase the sales of Vioxx and secure a greater share of the COX-2-market.

183. At all relevant times, defendants' statements and omissions were undertaken with the intent that the FDA, physicians, and consumers, including the plaintiffs, would rely on the defendant's statements and/or omissions.

184. At all relevant times, defendants knew of the growing public acceptance of the misinformation and misrepresentations regarding the safety and efficacy of Vioxx but remained silent because their appetite for significant future profits far outweighed its concern for the health and safety of the plaintiffs and others like them.

185. Plaintiffs' were prescribed and/or otherwise provided with Vioxx, and plaintiffs consumed Vioxx, and suffered ascertainable losses of money as a result of the defendants' use or employment of the methods, acts or practices alleged herein.

186. The aforesaid promotion and release of Vioxx into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentations, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connections with the sale or advertisement of such merchandise or services by defendants.

187. At all relevant times, defendants concealed, omitted, or minimized the side effects of Vioxx or provided mis-information about adverse reactions, risks and potential harms from Vioxx and succeeded in persuading consumers, including plaintiffs, to purchase and ingest Vioxx despite

the lack of safety and the risk of adverse medical reactions, including cardiovascular events and gastrointestinal effects.

188. At all relevant times, defendants' practice of promoting and marketing Vioxx created and reinforced a false impression as to the safety of Vioxx, thereby placing consumers, including plaintiffs, at risk of serious and potential lethal effects.

189. At all relevant times, Vioxx lacked appropriate warnings, and the packaging and labels used by defendant were misleading, inaccurate, incomplete and/or untimely.

190. Defendants violated their post-manufacture duty to warn which arose when Merck knew, or with reasonable care should have known, that Vioxx was injurious and sometimes fatal.

191. At the time when consumers purchased and ingested Vioxx, Merck intended that others would rely upon the concealment, suppression or omission of the risks of ingesting Vioxx.

192. Defendants' actions in connection with manufacturing, distributing, and marketing of Vioxx as set forth herein evidence a lack of good faith, honesty in fact and were not observant of fair dealing so as to constitute unconscionable commercial practices.

193. Defendants acted willfully, knowingly, intentionally, unconscionably and with reckless indifference when committing these acts of consumer fraud.

194. As a proximate result of the acts of consumer fraud set forth above, plaintiffs purchased an unsafe product and incurred monetary expense and the risk to themselves and members of their households that they would consume Vioxx and thereby suffer an increased risk of harm as previously set forth herein.

195. The conduct of the defendants, as set forth above, constitutes unfair, deceptive, unlawful, and/or unconscionable acts and/or practices prohibited under the New Jersey Consumer

Fraud Act, N.J.S.A. 56:8-2, et seq. and the Consumer Protection Statutes of the various states and prohibited under the Commonwealth of Pennsylvania's Consumer Protection Law, 73 Pa. Stat. Ann. § 201-2 et seq. and/or applicable New York and/or Minnesota laws and statutes.

196. As a direct and proximate result of defendants' unfair, deceptive, unlawful, and/or unconscionable acts or practices in violation of the aforesaid Consumer Protection Laws of New Jersey and the Commonwealth of Pennsylvania's Consumer Protection Law, 73 Pa. Stat. Ann. § 201-2 et seq. and/or other states, and/or applicable New York and/or Minnesota laws and statutes, injuries and damages were sustained by plaintiffs.

COUNT XII
UNJUST ENRICHMENT

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

197. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

198. Defendants accepted payment from plaintiffs for the purchase of Vioxx.

199. Plaintiffs did not receive a safe and effective drug for which they paid.

200. It would be inequitable for defendants to retain this money because plaintiffs did not in fact receive a safe and effective drug.

COUNT XIII
PUNITIVE DAMAGES

Plaintiffs vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

201. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

202. Based upon the above, a jury could conclude that the defendants knew of facts that created a high degree of risk of physical harm to the plaintiffs and that the defendants deliberately proceeded to act in conscious disregard or indifference to that risk, and therefore that an award of punitive damages is warranted.

COUNT XIV
LOSS OF CONSORTIUM

Plaintiff, Ronald J. Lang vs. Merck & Company, Inc., Peter S. Kim, Ph.D., David Anstice, Louis Sherwood, M.D. and Edward Scolnick, M.D.

203. Plaintiffs incorporate by reference each preceding and succeeding paragraph as though set forth fully at length herein.

204. Plaintiff, Ivan Lang's spouse, Ronald J. Lang, was at all times relevant herein, the husband of plaintiff, and as such, lives and cohabits with her.

205. By reason of the foregoing, plaintiff's spouse has necessarily paid and has become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.

206. By reason of the foregoing, plaintiff's spouse has been caused, presently and in the future, the loss of their husband/wife's companionship, services, society and the ability of said plaintiff's husband in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the plaintiff's have been caused treat mental aguish and suffering.

WHEREFORE, Plaintiffs, Mary Bowen, Ivan Lang and Ronald J. Lang, demand judgment against Defendant for damages including exemplary damages if applicable to which they are entitled by law, as well as all costs of this action, to the full extent of the law including:

1. judgment for plaintiffs and against defendant;

2. damages in the form of compensatory damages in excess of the jurisdictional limits, trebled on all applicable Counts;

3. physical pain and suffering of the Plaintiffs;

4. pre and post judgment interest at the lawful rate;

5. reasonable attorneys' fees and costs and expert fees;

6. a trial by jury on all issues of the case;

7. for any other relief as this court may deem equitable and just;

8. for any and all damages as a result of the loss of consortium to plaintiffs;

9. restitution of all purchase costs that Plaintiffs paid for Vioxx, disgorgement of Defendant's profits, and such other relief as provided by law;

10. exemplary and punitive damages in an amount in excess of the jurisdictional limits, trebled on all applicable Counts;

11. all Bill of Costs elements; and

12. such other relief this Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand that all issues of fact of this case be tried to a properly impaneled jury.

Dated: 7/5/05

BY: _____

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